



New Device Approvals

Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator - P010021

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator
Manufacturer: Ortho-Clinical Diagnostics, Inc
Address: 100 Indigo Creek Drive, Rochester NY 14626-5101
Approval Date: August 30, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010021a.pdf>

What is it? A test to detect hepatitis C virus (HCV) infection.

How does it work? A person's blood serum, being tested for anti-HCV, is placed into wells coated with HCV antigen (proteins from HCV). If there are anti-HCV in the blood, they stick to the antigen. The wells are washed to remove excess blood serum. Reagent Packs solutions are then added to the wells. If there are antibodies attached to the antigens, they react with the Reagent Pack solutions to produce light. The amount of light produced is measured and shows the presence anti-HCV in the patient's blood serum.

When is it used and what will it accomplish? This is the initial laboratory test used for people who might be infected with hepatitis C virus.

When should it not be used? This test should not be used to make a final diagnosis of infection with HCV. If this test is positive, more tests will be required to determine if the person is infected. This test should not be used for screening blood donors, because it has not been proven effective for this purpose. It should be used only when prescribed by a physician.

Additional information: Summary of Safety and Effectiveness and labeling will be available at:
<http://www.fda.gov/cdrh/pdf/p010021.html>

Other:

- Centers for Disease Control:
<http://www.cdc.gov/ncidod/diseases/hepatitis/c/index.htm>
- Liver Foundation site: (click on liver dysfunction & disease; click on hepatitis A, B, C, select hepatitis c)
<http://www.liverfoundation.org/html/livheal.dir/livheal.htm>

(Updated 11/30/2001)

